UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF INDIANA
SOUTH BEND DIVISION

LORI NICHOLSON and WILLIS WILLIAM NICHOLSON, **Plaintiffs,** **v.** **BIOMET, INC., et al.,** **Defendants.**	)	**CASE NO: 3:13-cv-00358-RLM-CAN** This Document Relates To: Case No. 3:12-MD-2391-RLM-CAN

Defendants Biomet, Inc., Biomet Orthopedics, LLC, Biomet Manufacturing Corporation and Biomet U.S. Reconstruction, LLC (collectively referred to herein as "Defendants"), by and through the undersigned counsel, state as follows:

1. Plaintiff Lori Nicholson ("Nicholson" or "Plaintiff') and Plaintiff Willis William Nicholson, by their attorneys, Schlesinger Law Offices, PA., complain against Defendants Biomet, Inc., Biomet Orthopedics, LLC, Biomet Manufacturing Corp., and Biomet US Reconstruction, LLC (collectively "Biomet" or "Defendants") as follows:

RESPONSE: The allegations in Paragraph 1 of Plaintiffs' Complaint are not directed at Defendants and therefore no response is required.

NATURE OF THE CASE

2. Plaintiff brings this product liability action against Defendants to redress the injuries sustained due to Defendants' defective hip system implanted in Plaintiff, which required revision surgery to remove Defendants' defective hip system.

RESPONSE: Defendants deny the allegations in Paragraph 2 of Plaintiffs' Complaint and specifically deny that the M^2a-Magnum™ Hip System is defective.

PARTIES

3. Plaintiffs are Iowa residents located at 620 1ST ST NW, Fort Dodge, Iowa 50501.

RESPONSE: Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 3 of Plaintiffs' Complaint and therefore deny the same.

4. Upon information and belief, Defendant Biomet, Inc. is an Indiana corporation, with its principal place of business in Warsaw, Indiana. Defendant Biomet, Inc. designed, manufactured, marketed, promoted, and sold the M2a Magnum Hip System that is the subject of this lawsuit.

RESPONSE: Defendants admit that Biomet, Inc. is a corporation organized under the laws of Indiana. Defendants further admit that Biomet, Inc.'s principal place of business is 56 East Bell Drive, Warsaw, Indiana. Defendants deny the remaining allegations in Paragraph 4 of Plaintiffs' Complaint.

5. Upon information and belief, Defendant Biomet Orthopedics, LLC is an Indiana limited liability corporation, with its principal place of business in Warsaw, Indiana. Defendant Biomet Orthopedics, LLC designed, manufactured, marketed, promoted, and sold the M2a Magnum Hip System that is the subject of this lawsuit

RESPONSE: Defendants admit that Biomet Orthopedics, LLC is a limited liability company organized under the laws of Indiana, with its principal place of business located at 56 East Bell Drive, Warsaw, Indiana. Defendants further admit that Biomet Orthopedics, LLC designed, manufactured, and sold a hip replacement product known as the M^2a-Magnum™ Hip Replacement System. Defendants deny all remaining allegations in Paragraph 5 of Plaintiffs' Complaint.

6. Upon information and belief, Defendant Biomet Manufacturing Corp. is an Indiana corporation with its principal place of business in Warsaw, Indiana. Defendant Biomet Manufacturing Corp. designed, manufactured, marketed, promoted, and sold the M2a Magnum Hip System that is the subject of this lawsuit.

RESPONSE: Defendants admit that Biomet Manufacturing Corporation is a corporation organized under the laws of Indiana, with its principal place of business at 56 East Bell Drive, Warsaw, Indiana. Defendants deny the remaining allegations in Paragraph 6 of Plaintiffs' Complaint.

7. Upon information and belief, Defendant Biomet US Reconstruction, LLC is an Indiana limited liability corporation, with its principal place of business in Warsaw, Indiana. Biomet US Reconstruction, LLC designed, manufactured, marketed, promoted, and sold the M2a Magnum Hip System that is the subject of this lawsuit.

RESPONSE: Defendants admit that Biomet U.S. Reconstruction, LLC is a limited liability company organized under the laws of Indiana, with its principal place of business located at 56 East Bell Drive Warsaw, Indiana. Defendants deny all remaining allegations in Paragraph 7 of Plaintiffs' Complaint.

8. Upon information and belief, at all relevant times, Defendants committed tortuous act(s) within the state of Iowa out of which act(s) these causes of action arise.

RESPONSE: Defendants deny the allegations in Paragraph 8 of Plaintiffs' Complaint.

JURISDICTION AND VENUE

9. The Court has jurisdiction under 28 U.S.C. § 1332 because this lawsuit is between citizens of different states and the amount in controversy exceeds $75,000.00, exclusive of costs

and interest. Plaintiffs are Iowa residents and domiciliaries; Defendants are all incorporated and/or have their principal place of business in Indiana.

RESPONSE: Defendants admit that Plaintiffs seek in excess of $75,000, but deny that Plaintiffs are entitled to any relief or damages. Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 9 of Plaintiffs' Complaint regarding Plaintiffs' citizenship and therefore deny the same. The remaining statutory allegations in Paragraph 9 of Plaintiffs' Complaint are legal conclusions to which no response is required.

10. Venue is proper in the Northern District Court in Iowa because Defendants committed tortuous act(s) within the state of Iowa out of which act(s) these causes of action arise. Plaintiff will directly file their action in this Court pursuant to the Court's February 15, 2013 Order, which permits direct filing of complaints. Plaintiffs' case would be subject to transfer to MDL No. 2391 by the Judicial Panel on Multistate Litigation pursuant to its October 2, 2012 Transfer Order. Plaintiffs will file a separate Notice of Related Action pursuant to Northern District of Indiana Rule 40-1(d).

RESPONSE: Based on the allegations in the Complaint, and pursuant to Paragraph III.D of this Court's Case Management Order dated February 15, 2013, Defendants admit that the venue for this action lies in the Northern District of Iowa. Defendants reserve the right to amend this Venue Statement following investigation and discovery.

FACTUAL ALLEGATIONS

11. The hip joint is where the femur connects to the pelvis. The joint is made up of the femoral head (a ball-like structure at the very top of the femur) rotating within the acetabulum (a cup-like structure at the bottom of the pelvis). In a healthy hip, both the femur

and the acetabulum are strong, and the rotation of the bones against each other is cushioned and lubricated by cartilage and fluids.

RESPONSE: Defendants admit that the hip is a ball-and-socket joint that allows the leg to move in a variety of positions. The femoral head (ball) rides in the acetabulum (socket). The joint is lined with a lubricating tissue called cartilage, which cushions the joint as it moves and bears weight. Defendants deny the remaining allegations in Paragraph 11 of Plaintiffs' Complaint.

12. A total hip replacement replaces the body's natural joint with an artificial one, usually made out of metal and plastic. A typical hip replacement system consists of four separate components: (1) a femoral stem; (2) a femoral head; (3) a plastic (polyethylene) linear; and (4) an acetabular shell. After the surgeon hollows out a patient's femur bone, the femoral stem is implanted. The femoral head is a metal ball that is fixed on top of the femoral stem. The femoral head forms the hip joint when it is placed inside the polyethylene linear and acetabular shell.

RESPONSE: Defendants admit that hip replacement surgery removes the arthritic ball of the upper femur (thighbone) as well as the damaged bone and cartilage from the hip socket. The damaged bone and cartilage are replaced with implants made from materials including metal alloys, polyethylene (plastic) or ceramic. The implants are designed to create a new, smoothly functioning joint that replaces painful bone-on-bone contact. Defendants deny the remaining allegations in Paragraph 12 of Plaintiffs' Complaint.

13. While most hip replacements use a polyethylene plastic acetabular liner, Biomet's M2a Magnum Hip System has a critical difference: it is a monoblock system which does not have an acetabular liner. Instead, the M2a Magnum Hip System forces metal to rub against

metal with the full weight and pressure of the human body. Because of Biomet's defective design for the M2a Magnum Hip System, hundreds of patients — including Plaintiff — have been forced to undergo surgeries to replace the failed hip implants.

RESPONSE: Defendants admit that the M^{2}a-Magnum™ Hip System does not require use of a polyethylene plastic liner. Defendants deny the remaining allegations in Paragraph 13 of Plaintiffs' Complaint.

14. The M2a Magnum Hip System suffers from a design or manufacturing defect that causes excessive amounts of cobalt and chromium to wear and corrode from the surface of the acetabular cup, from the femoral head, and from the taper adapter. These cobalt and chromium fragments prompt the body to react by rejecting the hip implant. This rejection often manifests with symptoms of pain, looseness, dislocation, and squeaking and popping sounds. Inside the hip joint, the metal reaction often causes fluids to accumulate and soft tissues and bone to die. Additionally, reports were received that M2a Magnum Hip System generated metal debris from wear, which can spread throughout the bone and tissue and cause severe inflammation and damage.

RESPONSE: Defendants deny the allegations in Paragraph 14 of Plaintiffs' Complaint.

15. Biomet failed to sufficiently test the design of the M2a Magnum Hip System, and the M2a Magnum Hip System was never approved by the FDA as being safe or effective for the products' intended purpose. Further, the M2a Magnum Hip System was not subject to the rigorous pre-market approval (PMA) testing and approval pursuant to 21 U.S.C. § 360(e). Instead, Defendants received FDA approval to market the M2a Magnum Hip System in the United States through the 510(k) pre-market notification process pursuant to 21 U.S.C. § 360(k), asserting that it was substantially equivalent to other metal-on-metal hip replacement systems

already on the market. This approval process is generally reserved for Class II devices. Accordingly, the M2a Magnum Hip System is not subject to federal preemption because it was not approved as an FDA Class III device.

RESPONSE: Defendants admit that the United States Food and Drug Administration cleared the M^2a-Magnum™ Hip System for marketing as a hip joint prosthesis under the FDA's Section 510(k) premarket notification process. Defendants deny the remaining allegations in Paragraph 15 of Plaintiffs' Complaint.

16. At the time the M2a Magnum Hip System was designed, tested, manufactured, marketed and introduced into the stream of commerce, safer more effective alternative designs of hip replacements existed and were available to patients.

RESPONSE: Defendants deny the allegations in Paragraph 16 of Plaintiffs' Complaint.

17. On numerous occasions, Biomet met with orthopedic surgeons throughout the United States, and other cities, including, upon information and belief, with Plaintiff's orthopedic surgeon, to promote the M2a Magnum Hip System. At some or all of these meetings, a representative or representatives of Biomet were present. During these meetings, Biomet assured the orthopedic surgeons that the M2a Magnum Hip System was safe, was the best product on the market, had an excellent track record, and a low acceptable failure rate. Biomet continued to "defend" the M2a Magnum Hip System even after they became aware of numerous and serious complications with the M2a Magnum Hip System. Biomet did not reveal (and instead concealed) their knowledge of numerous complications and other "bad data" during their meetings with orthopedic surgeons.

RESPONSE: Defendants deny the allegations in Paragraph 17 of Plaintiffs' Complaint.

18. Shortly after launching the M2a Magnum Hip System, reports of failures began flooding into Biomet. For example, in or about August 2004, Biomet received a complaint that a patient required and underwent surgery to remove and replace the M2a Magnum Hip System because it had become loose after only 3 years. Biomet closed its investigation of this complaint.

RESPONSE: Defendants deny the allegations in Paragraph 18 of Plaintiffs' Complaint.

19. Biomet received hundreds of similar complaints reporting that M2a Magnum Hip System failed, that that failure forced patients to undergo painful and risky surgeries to remove and replace the failed hip component. To date, more than 350 reports of adverse events associate with the M2a Magnum Hip System have been filed with the FDA.

RESPONSE: Defendants deny the allegations in Paragraph 19 of Plaintiffs' Complaint.

20. By the time Biomet sold the M2a Magnum Hip System to Plaintiff, numerous reports had been filed with the FDA reporting an adverse event associate with the M2a Magnum Hip System. Thus, Biomet was fully aware that the M2a Magnum Hip System was defective and that patients had been injured by that defect. Based on this information, Biomet should have recalled the M2a Magnum Hip System before it was sold to Plaintiff. Indeed, Biomet should have stopped selling the defective implant when Biomet became aware that the M2a Magnum Hip System had failed in several patients.

RESPONSE: Defendants deny the allegations in Paragraph 20 of Plaintiffs' Complaint.

21. Despite knowing that the M2a Magnum Hip System had a defect, and that it failed hundreds of times, causing hundreds of patients to undergo complicated, expensive, and painful revision surgeries with a prolonged recovery time, Biomet continued to sell the defective M2a Magnum Hip System. Biomet actively concealed the known defects from doctors and patients — including Plaintiff and Plaintiff's doctor.

RESPONSE: Defendants deny the allegations in Paragraph 21 of Plaintiffs' Complaint.

22. Ignoring the numerous reported M2a Magnum Hip System failures, Biomet continued to promote, market, and defend the defective M2a Magnum Hip System. For example, Biomet published marketing brochures touting the safety and durability of metal-on-metal implants and specifically, the M2a Magnum Hip System. Biomet gave these brochures to doctors around the world to encourage them to use the M2a Magnum Hip System.

RESPONSE: Defendants deny the allegations in Paragraph 22 of Plaintiffs' Complaint.

23. Despite its knowledge that the M2a Magnum Hip System was defective, Biomet also made several false representations about specific design elements of the M2a Magnum Hip System that it claimed made the M2a Magnum Hip System superior to other more safe hip implants on the market. Biomet claimed:

(a) "The M2a-Magnum™ Large Metal Articulation System offers optimal joint mechanic restoration and ultra low-wear rates in vivo," and

(b) "Many studies conducted over the last several decades have shown no definitive correlation of negative health issues to ion levels exhibited from metal-on-metal implants;"

(c) "[S]et the standard for performance and design in hip systems;"

(d) "[A]n ultra-high performance metal-on-metal articulation;"

(e) "[D]esigned specifically to address the issue of wear debris;"

(f) "[T]he right choice for use in young, highly active patients."

Additionally, Biomet promoted the M2a Magnum Hip System as "offering improved range of motion and joint stability" and employed gymnast, Mary Lou Retton to deliver the message in April 2006 for direct-to-consumer print, TV and radio advertising.

RESPONSE: Defendants deny the allegations in Paragraph 23 of Plaintiffs' Complaint.

24. Biomet's reason for concealing the defect in the M2a Magnum Hip System is clear. Hip implant sales are critically important to Biomet, and the M2a Magnum Hip System is one of Biomet's most profitable products. During the time period relevant to this Complaint, Biomet's management was trying to make Biomet appealing to investors, and in 2007, Biomet was purchased by a private equity firm for $10 billion.

RESPONSE: Defendants admit that a consortium of private equity firms purchased Biomet, Inc. in 2007. Defendants deny the remaining allegations in Paragraph 24 of Plaintiffs' Complaint.

25. Biomet chose corporate profits over patient safety. Rather than admit its M2a Magnum Hip System is defective, Biomet continued to promote, market, and sell the M2a Magnum Hip System. At present, Biomet continues to sell the defective M2a Magnum Hip System to unsuspecting patients without any warning about the risks or the failures reported to Biomet.

RESPONSE: Defendants deny the allegations in Paragraph 25 of Plaintiffs' Complaint.

26. On or about July 10, 2007 Plaintiff underwent a surgical procedure to implant the M2a Magnum Hip System in her left hip. Dr. Emile Li performed the surgery at the Wright Medical Center in Clarion, Iowa.

RESPONSE: Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 26 of Plaintiffs' Complaint and therefore deny the same.

27. By this time, numerous reports of adverse events associated with M2a Magnum Hip System had been filed with the FDA, and Biomet knew the M2a Magnum Hip System was

defective. Nevertheless, Biomet refused to disclose that information to Plaintiff, her physicians, or the public. Instead, Biomet misrepresented to Plaintiff and her orthopedic surgeon that the M2a Magnum Hip System was safe and effective. Relying on Biomet's representations, Plaintiff's orthopedic surgeon decided to use the M2a Magnum Hip System. But for Biomet's misrepresentations, Plaintiff would not, and Plaintiff's orthopedic surgeon would not have used the M2a Magnum Hip System for Plaintiff's hip replacement surgery.

RESPONSE: Defendants deny the allegations in Paragraph 27 of Plaintiffs' Complaint.

28. As a result of the defective design, manufacture and composition of the M2a Magnum Hip System, and its accompanying warnings and instructions (or lack thereof), Plaintiff's hip implant failed, causing her severe pain.

RESPONSE: Defendants deny the allegations in Paragraph 28 of Plaintiffs' Complaint.

29. Plaintiffs M2a Magnum Hip System loosened, causing increased strain on the acetabulum consistent with increased ionic metal-on-metal wear contributing to a pseudo cyst. In addition Plaintiff's chromium levels were 6 times that of the normal rate.

RESPONSE: Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 29 of Plaintiffs' Complaint and therefore deny the same.

30. Plaintiff underwent revision surgery on June 19, 2012, to remove the failed M2a Magnum Hip System from Plaintiff's body. Revision surgeries are generally more complex than the original hip replacement surgery, often because there is a reduced amount of bone in which to place the new hip implants. Revision surgeries also usually take longer than the hip replacement surgery and the revision surgery has a higher rate of complications.

RESPONSE: Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 30 of Plaintiffs' Complaint regarding Plaintiff's surgical procedure and therefore deny the same. Defendants deny all remaining allegations in Paragraph 30 of Plaintiffs' Complaint.

31. Plaintiffs revision surgery was performed by Dr. Li at the Wright Medical Center in Clarion, Iowa. Dr. Li replaced the failed M2a Magnum Hip System with a metal-on-poly hip system.

RESPONSE: Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 31 of Plaintiffs' Complaint and therefore deny the same.

32. Having to go through a revision surgery, has subjected Plaintiff to greater risks of future complications than she had before the revision surgery. Studies found that a revision surgery causes a much higher risk of dislocation compared with an original hip replacement surgery. A study by Charlotte Philips and her colleagues at Brigham and Women's Hospital in Boston showed that 14.4 percent of patients who had revision surgery suffered from a dislocation compared with 3.9 percent of patients who had an original hip replacement surgery. In other words, hip replacement patients who had a revision surgery are almost four times more likely to suffer from a hip dislocation than those who have not. (Phillips CB, et al. Incidence rates of dislocation, pulmonary embolism, and deep infection during the first six months after elective total hip replacement. American Journal of Bone and Joint Surgery 2003; 85:20-26).

RESPONSE: Defendants admit that Charlotte Phillips published an article regarding hip replacement surgery in American Journal of Bone and Joint Surgery and that the publication

speaks for itself. Defendants deny the remaining allegations in Paragraph 32 of Plaintiffs' Complaint.

33. As a direct and proximate result of the failure of her M2a Magnum Hip System and Biomet's wrongful conduct, Plaintiff sustained and continues to suffer economic damages (including, medical and hospital expenses), severe and possibly permanent injuries, pain, suffering and emotional distress. As a result Plaintiff has sustained and will continue to sustain damages in an amount to be proven at trial, but which will far exceed the $75,000.00 jurisdictional minimum of this Court.

RESPONSE: Defendants deny the allegations in Paragraph 33 of Plaintiffs' Complaint.

FIRST CAUSE OF ACTION

(Strict Products Liability — Manufacturing Defect)

34. Plaintiff incorporates all of the preceding paragraphs of this Complaint as if fully set forth here and further alleges as follows:

RESPONSE: Defendants incorporate by reference their responses to the above paragraphs as if fully set forth herein.

35. Defendants are the manufacturers, designers, distributors, sellers, and/or suppliers of the M2a Magnum Hip System that was surgically implanted in Plaintiff.

RESPONSE: Defendants admit that Biomet Orthopedics, LLC is engaged in the design, manufacture, sale, and distribution of M^2a-Magnum™ Hip Systems. Defendants deny the remaining allegations in Paragraph 35 of Plaintiffs' Complaint.

36. The M2a Magnum Hip System manufactured, designed, sold, distributed, supplied and/or placed in the stream of commerce by Defendants was defective in its manufacture and construction when it left Defendants' hands because it deviated from product

specifications and/or applicable federal requirements for these medical devices, posing a serious risk of injury and death.

RESPONSE: Defendants deny the allegations in Paragraph 36 of Plaintiffs' Complaint.

37. As a direct and proximate result of Plaintiff's use of Defendants' M2a Magnum Hip System as manufactured, designed, sold, supplied and introduced into the stream of commerce by Defendants and/or the failure to comply with federal requirements, Plaintiff suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future. The M2a Magnum Hip System is not subject to federal preemption because it was not approved as an FDA Class III device.

RESPONSE: Defendants deny the allegations in Paragraph 37 of Plaintiffs' Complaint.

38. Defendants' conduct as described above, was extreme and outrageous. Defendants risked the lives of recipients of their products, including Plaintiff's, with knowledge of the safety and efficacy problems and suppressed this knowledge from the general public. Defendants knew or should have known of the serious health risks it created and/or the failure to comply with federal requirements. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting recipients of Defendants' M2a Magnum Hip System. Defendants' outrageous conduct warrants an award of punitive damages.

RESPONSE: Defendants deny the allegations in Paragraph 38 of Plaintiffs' Complaint.

39. Plaintiff seeks actual and punitive damages from Defendants as alleged herein.

RESPONSE: Defendants deny that Plaintiffs are entitled to the relief requested or any relief at all.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems just and proper.

RESPONSE: Defendants deny that Plaintiffs are entitled to the relief requested or any relief at all.

SECOND CAUSE OF ACTION

(Strict Products Liability — Design Defect)

40. Plaintiff incorporates all of the preceding paragraphs of this Complaint as if fully set forth here and further alleges as follows:

RESPONSE: Defendants incorporate by reference their responses to the above paragraphs as if fully set forth herein.

41. Defendants are the manufacturers, designers, distributors, sellers, and/or suppliers of the M2a Magnum Hip System that was surgically implanted in Plaintiff.

RESPONSE: Defendants admit that Biomet Orthopedics, LLC is engaged in the design, manufacture, sale, and distribution of M^2a-Magnum™ Hip Systems. Defendants deny the remaining allegations in Paragraph 41 of Plaintiffs' Complaint.

42. The M2a Magnum Hip System was in an unsafe, defective and inherently dangerous condition for users such as Plaintiff.

RESPONSE: Defendants deny the allegations in Paragraph 42 of Plaintiffs' Complaint.

43. The M2a Magnum Hip System was in an unsafe, defective and inherently dangerous condition at the time it left Defendants' possession.

RESPONSE: Defendants deny the allegations in Paragraph 43 of Plaintiffs' Complaint.

44. At all times relevant, the M2a Magnum Hip System was expected to and did reach the usual consumers, handlers, and persons coming into contact with the M2a Magnum Hip System without substantial change in the condition in which it was designed, produced, manufactured, sold, distributed and marketed by Defendants.

RESPONSE: Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 44 of Plaintiffs' Complaint and therefore deny the same.

45. The M2a Magnum Hip System's unsafe, defective, and inherently dangerous condition injured Plaintiff.

RESPONSE: Defendants deny the allegations in Paragraph 45 of Plaintiffs' Complaint.

46. The M2a Magnum Hip System failed to perform as safely as an ordinary consumer would expect when used in an intended or reasonably foreseeable manner.

RESPONSE: Defendants deny the allegations in Paragraph 46 of Plaintiffs' Complaint.

47. Plaintiff's injuries resulted from use of the M2a Magnum Hip System that was both intended and reasonably foreseeable by Defendants.

RESPONSE: Defendants deny the allegations in Paragraph 47 of Plaintiffs' Complaint.

48. At all times relevant, the M2a Magnum Hip System posed a foreseeable risk of danger inherent in the design, which greatly outweighed the benefits of that design.

RESPONSE: Defendants deny the allegations in Paragraph 48 of Plaintiffs' Complaint.

49. At all times relevant, the M2a Magnum Hip System was defective and unsafe, and Defendants knew or had reason to now that said product was defective and unsafe, especially when used in the form and manner as provided by Defendants.

RESPONSE: Defendants deny the allegations in Paragraph 49 of Plaintiffs' Complaint.

50. At all times relevant, Defendants knew, or should have known, that the M2a Magnum Hip System was in a defective condition and was and is inherently dangerous and unsafe.

RESPONSE: Defendants deny the allegations in Paragraph 50 of Plaintiffs' Complaint.

51. When implanted into Plaintiff, the M2a Magnum Hip System was used for the purpose and in a manner normally intended, namely for use as a hip replacement device.

RESPONSE: Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 51 of Plaintiffs' Complaint and therefore deny the same.

52. Defendants, with this knowledge, voluntarily designed their M2a Magnum Hip System in a dangerous condition for use by the public and, in particular, Plaintiff.

RESPONSE: Defendants deny the allegations in Paragraph 52 of Plaintiffs' Complaint.

53. At all times relevant, the M2a Magnum Hip System lacked utility for any group of users, including Plaintiff.

RESPONSE: Defendants deny the allegations in Paragraph 53 of Plaintiffs' Complaint.

54. The M2a Magnum Hip System provided no net benefit to any class of patients, including Plaintiff.

RESPONSE: Defendants deny the allegations in Paragraph 54 of Plaintiffs' Complaint.

55. Defendants had a duty to create a product that was not unreasonably dangerous for its normal, intended use.

RESPONSE: Defendants state that Paragraph 55 of Plaintiffs' Complaint contains legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 55 of Plaintiffs' Complaint.

56. Defendants failed to complete adequate pre-market testing and post-market surveillance on the M2a Magnum Hip System.

RESPONSE: Defendants deny the allegations in Paragraph 56 of Plaintiffs' Complaint.

57. Defendants designed, researched, manufactured, tested, advertised, promoted, marketed, sold and distributed a defective product which, when used in its intended or reasonably foreseeable manner, created an unreasonable risk to the health of consumers and to Plaintiff in particular, and Defendants are therefore strictly liable for the injuries sustained by Plaintiff.

RESPONSE: Defendants deny the allegations in Paragraph 57 of Plaintiffs' Complaint.

58. Defendants are strictly liable for Plaintiff's injuries in the following ways:

(a) the M2a Magnum Hip System as designed, manufactured, sold and supplied by Defendants, was defectively designed and placed into the stream of commerce by Defendants in a defective and unreasonably dangerous condition;

(b) Defendants failed to properly market, design, manufacture, distribute, supply and sell the M2a Magnum Hip System;

(c) Defendants failed to adequately test the M2a Magnum Hip System; and

(d) A feasible alternative design existed that was capable of preventing Plaintiff's injuries.

RESPONSE: Defendants deny the allegations in Paragraph 58 of Plaintiffs' Complaint, and its subparagraphs (a) – (d).

59. As a direct and proximate result of Defendants' placement of the defective M2a Magnum Hip System into the stream of commerce, Plaintiff suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic

loss in the future. The M2a Magnum Hip System is not subject to federal preemption because it was not approved as an FDA Class III device.

RESPONSE: Defendants deny the allegations in Paragraph 59 of Plaintiffs' Complaint.

60. Defendants' conduct as described above, was extreme and outrageous. Defendants risked the lives of recipients of their products, including Plaintiff's, with knowledge of the safety and efficacy problems and suppressed this knowledge from the general public. Defendants knew or should have known of the serious health risks it created and/or the failure to comply with federal requirements. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting recipients of Defendants' M2a Magnum Hip System. Defendants' outrageous conduct warrants an award of punitive damages.

RESPONSE: Defendants deny the allegations in Paragraph 60 of Plaintiffs' Complaint.

61. Plaintiff seeks actual and punitive damages from Defendants as alleged herein.

RESPONSE: Defendants deny that Plaintiffs are entitled to the relief requested or any relief at all.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems just and proper.

RESPONSE: Defendants deny that Plaintiffs are entitled to the relief requested or any relief at all.

THIRD CAUSE OF ACTION

(Strict Products Liability — Defect Due To Nonconformance With Representations)

62. Plaintiff incorporates all of the preceding paragraphs of this Complaint as if fully set forth here and further alleges as follows:

RESPONSE: Defendants incorporate by reference their responses to the above paragraphs as if fully set forth herein.

63. Defendants are the manufacturers, designers, distributors, sellers, and/or suppliers of the M2a Magnum Hip System.

RESPONSE: Defendants admit that Biomet Orthopedics, LLC is engaged in the design, manufacture, sale, and distribution of M^2a-Magnum™ Hip Systems. Defendants deny all remaining allegations in Paragraph 63 of Plaintiffs' Complaint.

64. The M2a Magnum Hip System, manufactured and supplied by Defendants was defective in that, when it left Defendants' hands, the M2a Magnum Hip System did not conform to Defendants' representations concerning the product and/or with applicable federal requirements.

RESPONSE: Defendants deny the allegations in Paragraph 64 of Plaintiffs' Complaint.

65. Defendants made representations to consumers regarding the character or quality of the M2a Magnum Hip System, including but not limited to statements that the M2a Magnum Hip System was a safe and durable replacement system. Defendants further asserted that the "Biomet metal-on-metal (MoM) M2a Magnum Large Metal articulation system offers optimal joint mechanic restoration and ultra low-wear rates in vivo. Many studies conducted over the last several decades have shown no definitive correlation of negative health issues to ion levels exhibited from metal-on-metal implants."

RESPONSE: Defendants admit that Biomet Orthopedics, LLC marketed the M^2a-Magnum™ consistent with all laws and regulations. Defendants deny all remaining allegations in Paragraph 65 of Plaintiffs' Complaint.

66. Plaintiff and/or her physicians justifiably relied upon Defendants' representations regarding the M2a Magnum Hip System when they selected Biomet orthopedic products to be used in surgery.

RESPONSE: Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 66 of Plaintiffs' Complaint regarding Plaintiff's and Plaintiff's physician's reliance and therefore deny the same. Defendants deny all remaining allegations in Paragraph 66 of Plaintiffs' Complaint.

67. As a direct and proximate result of Plaintiff's use of the M2a Magnum Hip System, and Plaintiff's and/or Plaintiff's healthcare providers' reliance on Defendants' representations regarding the character and quality of the M2a Magnum Hip System and/or the failure to comply with federal requirements, Plaintiff suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future. The M2a Magnum Hip System is not subject to federal preemption because it was not approved as an FDA Class III device.

RESPONSE: Defendants deny the allegations in Paragraph 67 of Plaintiffs' Complaint.

68. Defendants' conduct as described above, was extreme and outrageous. Defendants risked the lives of recipients of their products, including Plaintiff's, with knowledge of the safety and efficacy problems and suppressed this knowledge from the general public. Defendants knew or should have known of the serious health risks it created and/or the failure to comply with federal requirements. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting recipients of Defendants' M2a Magnum Hip System. Defendants' outrageous conduct warrants an award of punitive damages.

RESPONSE: Defendants deny the allegations in Paragraph 68 of Plaintiffs' Complaint.

69. Plaintiff seeks actual and punitive damages from Defendants as alleged herein.

RESPONSE: Defendants deny that Plaintiffs are entitled to the relief requested or any relief at all.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems just and proper.

RESPONSE: Defendants deny that Plaintiffs are entitled to the relief requested or any relief at all.

FOURTH CAUSE OF ACTION

(Strict Products Liability — Failure To Warn)

70. Plaintiff incorporates all of the preceding paragraphs of this Complaint as if fully set forth here and further alleges as follows:

RESPONSE: Defendants incorporate by reference their responses to the above paragraphs as if fully set forth herein.

71. The M2a Magnum Hip System was defective and unreasonably dangerous when it left the possession of Defendants in that it contained warnings insufficient to alert consumers, including Plaintiff, of the dangerous risks and reactions associated with the M2a Magnum Hip System including but not limited to the risks of developing serious and dangerous side effects, including but not limited to component loosening, component mal-alignment, infections, fracture of the bone, dislocation, metal sensitivity and pain, irritation and discomfort, as well as the need for additional procedures to remove and replace the M2a Magnum Hip System, as well as other severe and permanent health consequences, notwithstanding, Defendants' knowledge of an increased risk of these injuries and side effects over other hip arthroplasty devices.

RESPONSE: Defendants deny the allegations in Paragraph 71 of Plaintiffs' Complaint.

72. At the time Plaintiff received and/or used the M2a Magnum Hip System, the M2a Magnum Hip System was being used for the purposes and in a manner normally intended, namely for hip arthroplasty.

RESPONSE: Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 72 of Plaintiffs' Complaint and therefore deny the same.

73. Plaintiff could not, by the exercising, reasonable care, have discovered the defects herein mentioned and perceived their danger.

RESPONSE: Defendants deny the allegations in Paragraph 73 of Plaintiffs' Complaint.

74. Defendants, as manufacturers and/or distributors of the M2a Magnum Hip System, are held to the level of knowledge of an expert in the field.

RESPONSE: Defendants state Paragraph 74 of Plaintiffs' Complaint contains legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 74 of Plaintiffs' Complaint.

75. Defendants' warnings were not accurate or clear, and/or were ambiguous.

RESPONSE: Defendants deny the allegations in Paragraph 75 of Plaintiffs' Complaint.

76. Defendants' warnings failed to properly warn physicians of the increased risks, subjecting Plaintiff to risks that exceeded the benefits of the M2a Magnum Hip System, including but not limited to component loosening, component mal-alignment, infections, fracture of the bone, dislocation, metal sensitivity and pain irritation and discomfort, as well as the need for additional procedures to remove and replace the M2a Magnum Hip System, as well as other severe and permanent health consequences, notwithstanding Defendants' knowledge of an

increased risk of these injuries and side effects over other hip arthroplasty devices. Defendants also failed to provide timely and adequate post-marketing warnings and instructions after they knew of the risk of injury associated with the M2a Magnum Hip System.

RESPONSE: Defendants deny the allegations in Paragraph 76 of Plaintiffs' Complaint.

77. Plaintiff, individually and through her physicians, reasonably relied upon Defendants' skill, superior knowledge and judgment.

RESPONSE: Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 77 of Plaintiffs' Complaint regarding Plaintiff's and Plaintiff's physician's reliance and therefore deny the same. Defendants deny all remaining allegations in Paragraph 77 of Plaintiffs' Complaint.

78. Defendants had a continuing duty to warn Plaintiff of the dangers associated with the M2a Magnum Hip System.

RESPONSE: Defendants state that Paragraph 78 of Plaintiffs' Complaint contains legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 78 of Plaintiffs' Complaint.

79. Had Plaintiff received adequate warnings regarding the risks of the M2a Magnum Hip System, she would not have used it.

RESPONSE: Defendants deny the allegations in Paragraph 79 of Plaintiffs' Complaint.

80. As a direct and proximate result of Plaintiff's use of the M2a Magnum Hip System, and Plaintiff's reliance on Defendants' representations regarding the character and quality of the M2a Magnum Hip System and/or the failure to comply with federal requirements, Plaintiff suffered serious physical injury, harm, damages and economic loss and will continue to

suffer such harm, damages and economic loss in the future. The M2a Magnum Hip System is not subject to federal preemption because it was not approved as an FDA Class III device.

RESPONSE: Defendants deny the allegations in Paragraph 80 of Plaintiffs' Complaint.

81. Defendants' conduct as described above, was extreme and outrageous. Defendants risked the lives of recipients of their products, including Plaintiff's, with knowledge of the safety and efficacy problems and suppressed this knowledge from the general public. Defendants knew or should have known of the serious health risks it created and/or the failure to comply with federal requirements. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting recipients of Defendants' M2a Magnum Hip System. Defendants' outrageous conduct warrants an award of punitive damages.

RESPONSE: Defendants deny the allegations in Paragraph 81 of Plaintiffs' Complaint.

82. Plaintiff seeks actual and punitive damages from Defendants as alleged herein.

RESPONSE: Defendants deny that Plaintiffs are entitled to the relief requested or any relief at all.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems just and proper.

RESPONSE: Defendants deny that Plaintiffs are entitled to the relief requested or any relief at all.

FIFTH CAUSE OF ACTION

(Negligence)

83. Plaintiff incorporates all of the preceding paragraphs of this Complaint as if fully set forth here and further alleges as follows:

RESPONSE: Defendants incorporate by reference their responses to the above paragraphs as if fully set forth herein.

84. Defendants had a duty to exercise reasonable care in designing, researching, manufacturing, marketing, supplying, promoting, sale, testing, quality assurance, quality control, and/or distribution of the M2a Magnum Hip System into the stream of commerce, including a duty to assure that the device would not cause those who had it surgically implanted to suffer adverse harmful effects from it.

RESPONSE: Defendants state that Paragraph 84 of Plaintiffs' Complaint contains legal conclusions to which no response is required. To the extent a response is required, Defendants deny the allegations in Paragraph 84 of Plaintiffs' Complaint.

85. Defendants failed to exercise reasonable care in designing, researching, manufacturing, marketing, supplying promoting, sale, testing, quality assurance, quality control, and/or distribution of the M2a Magnum Hip System into interstate commerce in that Defendants knew or should have known that the M2a Magnum Hip System caused significant bodily harm, including but not limited to, partial or complete loss of mobility, loss of range of motion, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for a revision surgery to replace the device with the increased risks of complications and death from such further surgery. Defendants knew or should have known the M2a Magnum Hip System was unsafe and/or failed to comply with federal requirements.

RESPONSE: Defendants deny the allegations in Paragraph 85 of Plaintiffs' Complaint.

86. Despite the fact that Defendants knew or should have known that the M2a Magnum Hip System posed a serious risk of bodily harm to consumers, Defendants continued to

manufacture and market the M2a Magnum Hip System for use by consumer and/or continued to fail to comply with federal requirements.

RESPONSE: Defendants deny the allegations in Paragraph 86 of Plaintiffs' Complaint.

87. Defendants knew or should have known that consumers such as Plaintiff would suffer foreseeable injury, and/or be at increased risk of suffering injury as a result of Defendants' failure to exercise ordinary care as described above, including the failure to comply with federal requirements.

RESPONSE: Defendants deny the allegations in Paragraph 87 of Plaintiffs' Complaint.

88. As a direct and proximate result of Defendants' negligence, Plaintiff suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages, and economic loss in the future. The M2a Magnum Hip System is not subject to federal preemption because it was not approved as an FDA Class III device.

RESPONSE: Defendants deny the allegations in Paragraph 88 of Plaintiffs' Complaint.

89. Defendants' conduct as described above, was extreme and outrageous. Defendants risked the lives of recipients of their products, including Plaintiff's, with knowledge of the safety and efficacy problems and suppressed this knowledge from the general public. Defendants knew or should have known of the serious health risks it created and/or the failure to comply with federal requirements. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting recipients of Defendants' M2a Magnum Hip System. Defendants' outrageous conduct warrants an award of punitive damages.

RESPONSE: Defendants deny the allegations in Paragraph 89 of Plaintiffs' Complaint.

90. Plaintiff seeks actual and punitive damages from Defendants as alleged herein.

RESPONSE: Defendants deny that Plaintiffs are entitled to the relief requested or any relief at all.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems just and proper.

RESPONSE: Defendants deny that Plaintiffs are entitled to the relief requested or any relief at all.

SIXTH CAUSE OF ACTION

(Breach Of Express Warranty)

91. Plaintiff incorporates all of the preceding paragraphs of this Complaint as if fully set forth here and further alleges as follows:

RESPONSE: Defendants incorporate by reference their responses to the above paragraphs as if fully set forth herein.

92. Defendants expressly warranted that the M2a Magnum Hip System was a safe and effective orthopedic device for those patients requiring a hip replacement.

RESPONSE: Defendants deny the allegations in Paragraph 92 of Plaintiffs' Complaint.

93. The M2a Magnum Hip System manufactured and sold by Defendants did not conform to these express representations because it caused serious injury to Plaintiff when used as recommended and directed.

RESPONSE: Defendants deny the allegations in Paragraph 93 of Plaintiffs' Complaint.

94. As a direct and proximate result of Defendants' breach of warranty, Plaintiff suffered serious physical injury, harm, damages and economic loss and will continue to suffer

such harm, damages and economic loss in the future. The M2a Magnum Hip System is not subject to federal preemption because it was not approved as an FDA Class III device.

RESPONSE: Defendants deny the allegations in Paragraph 94 of Plaintiffs' Complaint.

95. Defendants' conduct as described above, was extreme and outrageous. Defendants risked the lives of recipients of their products, including Plaintiff's, with knowledge of the safety and efficacy problems and suppressed this knowledge from the general public. Defendants knew or should have known of the serious health risks it created and/or the failure to comply with federal requirements. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting recipients of Defendants' M2a Magnum Hip System. Defendants' outrageous conduct warrants an award of punitive damages.

RESPONSE: Defendants deny the allegations in Paragraph 95 of Plaintiffs' Complaint.

96. Plaintiff seeks actual and punitive damages from Defendants as alleged herein.

RESPONSE: Defendants deny that Plaintiffs are entitled to the relief requested or any relief at all.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems just and proper.

RESPONSE: Defendants deny that Plaintiffs are entitled to the relief requested or any relief at all.

SEVENTH CAUSE OF ACTION

(Breach Of Implied Warranty Of Merchantability)

97. Plaintiff incorporates all of the preceding paragraphs of this Complaint as if fully set forth here and further alleges as follows:

RESPONSE: Defendants incorporate by reference their responses to the above paragraphs as if fully set forth herein.

98. At the time Defendants designed, manufactured, marketed, sold, and distributed the M2a Magnum Hip System for Plaintiff's use, Defendants knew of the use for which the M2a Magnum Hip System was intended and impliedly warranted the product to be of merchantable quality and safe for such use and that its design, manufacture, labeling and marketing complied with all applicable federal requirements.

RESPONSE: Defendants deny that they made any implied warranty to Plaintiffs and deny the remaining allegations in Paragraph 98 of Plaintiffs' Complaint.

99. Plaintiff and/or her physicians reasonably relied upon Defendants' skill and judgment as to whether the M2a Magnum Hip System was of merchantable quality and safe for its intended use and upon Defendants' implied warranty as to such matters, including that it was in compliance with federal requirements.

RESPONSE: Defendants deny that they made any implied warranty to Plaintiffs and deny the remaining allegations in Paragraph 99 of Plaintiffs' Complaint.

100. Contrary to Defendants' implied warranties, the M2a Magnum Hip System was not of merchantable quality or safe for the ordinary purposes for which the M2a Magnum Hip System was to be used, because the M2a Magnum Hip System was unreasonably dangerous and/or not reasonably fit for its intended, anticipated, or reasonably foreseeable use as described above.

RESPONSE: Defendants deny that they made any implied warranty to Plaintiffs and deny the remaining allegations in Paragraph 100 of Plaintiffs' Complaint.

101. As a direct and proximate result of Defendants' breach of warranty of merchantability, Plaintiff suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future. The M2a Magnum Hip System is not subject to federal preemption because it was not approved as an FDA Class III device.

RESPONSE: Defendants deny the allegations in Paragraph 101 of Plaintiffs' Complaint.

102. Defendants' conduct as described above, was extreme and outrageous. Defendants risked the lives of recipients of their products, including Plaintiff's, with knowledge of the safety and efficacy problems and suppressed this knowledge from the general public. Defendants knew or should have known of the serious health risks it created and/or the failure to comply with federal requirements. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting recipients of Defendants' M2a Magnum Hip System. Defendants' outrageous conduct warrants an award of punitive damages.

RESPONSE: Defendants deny the allegations in Paragraph 102 of Plaintiffs' Complaint.

103. Plaintiff seeks actual and punitive damages from Defendants as alleged herein.

RESPONSE: Defendants deny that Plaintiffs are entitled to the relief requested or any relief at all.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems just and proper.

RESPONSE: Defendants deny that Plaintiffs are entitled to the relief requested or any relief at all.

EIGHTH CAUSE OF ACTION

(Breach Of Implied Warranty Of Fitness For A Particular Purpose)

104. Plaintiff incorporates all of the preceding paragraphs of this Complaint as if fully set forth here and further alleges as follows:

RESPONSE: Defendants incorporate by reference their responses to the above paragraphs as if fully set forth herein.

105. Defendants designed, manufactured, tested, marketed and distributed the M2a Magnum Hip System into the stream of commerce.

RESPONSE: Defendants admit that Biomet Orthopedics, LLC is engaged in the design, manufacture, sale, and distribution of M^2a-Magnum™ Hip Systems. Defendants deny the remaining allegations in Paragraph 105 of Plaintiffs' Complaint.

106. At the time Defendants designed, manufactured, tested, marketed and distributed the M2a Magnum Hip System into the stream of commerce, Defendants knew the particular use for which the M2a Magnum Hip System was intended, and impliedly warranted the M2a Magnum Hip System to be safe for such use.

RESPONSE: Defendants deny that they made any implied warranty to Plaintiffs and deny the remaining allegations in Paragraph 106 of Plaintiffs' Complaint.

107. Plaintiff and/or her physicians reasonably relied upon Defendants' skill and judgment as to whether the M2a Magnum Hip System was safe for its intended use.

RESPONSE: Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations regarding Plaintiff's and Plaintiff's physician's reliance,

and therefore deny the same. Defendants deny all remaining allegations in Paragraph 107 of Plaintiffs' Complaint.

108. Contrary to Defendants' implied warranty of fitness for a particular purpose, the M2a Magnum Hip System was not safe for its intended use or fit for the particular purpose for which it was designed, manufactured, tested, distributed or sold — for use and implantation as a total hip replacement system, because the M2a Magnum Hip System was unreasonably dangerous and/or not reasonably fir for its intended, anticipated or reasonably foreseeable use as described above.

RESPONSE: Defendants deny that they made any implied warranty to Plaintiffs and deny the remaining allegations in Paragraph 108 of Plaintiffs' Complaint.

109. As a direct and proximate result of Defendants' breach of implied warranty of fitness for a particular purpose, Plaintiff suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future. The M2a Magnum Hip System is not subject to federal preemption because it was not approved as an FDA Class III device.

RESPONSE: Defendants deny the allegations in Paragraph 109 of Plaintiffs' Complaint.

110. Defendants' conduct as described above, was extreme and outrageous. Defendants risked the lives of recipients of their products, including Plaintiff's, with knowledge of the safety and efficacy problems and suppressed this knowledge from the general public. Defendants knew or should have known of the serious health risks it created and/or the failure to comply with federal requirements. Defendants made conscious decisions not to redesign, re-

label, warn or inform the unsuspecting recipients of Defendants' M2a Magnum Hip System. Defendants' outrageous conduct warrants an award of punitive damages.

RESPONSE: Defendants deny the allegations in Paragraph 110 of Plaintiffs' Complaint.

111. Plaintiff seeks actual and punitive damages from Defendants as alleged herein.

RESPONSE: Defendants deny that Plaintiffs are entitled to the relief requested or any relief at all.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems just and proper.

RESPONSE: Defendants deny that Plaintiffs are entitled to the relief requested or any relief at all.

NINTH CAUSE OF ACTION

(Negligent Misrepresentation)

112. Plaintiff incorporates all of the preceding paragraphs of this Complaint as if fully set forth here and further alleges as follows:

RESPONSE: Defendants incorporate by reference their responses to the above paragraphs as if fully set forth herein.

113. Defendants supplied false information to the public, to Plaintiff and/or her physicians regarding the high-quality, safety and effectiveness of the M2a Magnum Hip System, including statements of low wear, excellent stability, optimal clearance, high survivorship rate, and low revision rate, and high superiority over other metal on metal hip implants. Defendants provided this false information to induce the public, Plaintiff and/or Plaintiff's physicians to

purchase and/or use and implant the M2a Magnum Hip System. In the exercise of reasonable care, Defendants should have known that its M2a Magnum Hip System failed to comply with federal requirements for safe design and manufacture and or/ was in other ways out of specification.

RESPONSE: Defendants deny the allegations in Paragraph 113 of Plaintiffs' Complaint.

114. Defendants knew or should have known that the information they supplied, as set forth above, would induce Plaintiff and/or Plaintiff's physicians to purchase and use the M2a Magnum Hip System was false and misleading.

RESPONSE: Defendants deny the allegations in Paragraph 114 of Plaintiffs' Complaint.

115. Defendants were negligent in obtaining or communicating this false information. Defendants negligently misrepresented to Plaintiff and/or Plaintiff's physicians that the M2a Magnum Hip System was safe and met all applicable design and manufacturing requirements.

RESPONSE: Defendants deny the allegations in Paragraph 115 of Plaintiffs' Complaint.

116. Plaintiff and/or Plaintiff's physicians reasonably relied on the false information and omissions supplied by Defendants, as set forth above, to Plaintiff's detriment by causing the M2a Magnum Hip System to be purchased and implanted in Plaintiff.

RESPONSE: Defendants deny the allegations in Paragraph 116 of Plaintiffs' Complaint.

117. As a direct and proximate result of Defendants' negligent misrepresentations and omissions and/or Defendants' failure to disclose its violations of federal requirements applicable

to the M2a Magnum Hip System, Plaintiff used Defendants' M2a Magnum Hip System and Plaintiff suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future. The M2a Magnum Hip System is not subject to federal preemption because it was not approved as an FDA Class III device.

RESPONSE: Defendants deny the allegations in Paragraph 117 of Plaintiffs' Complaint.

118. Defendants' conduct as described above, was extreme and outrageous. Defendants risked the lives of recipients of their products, including Plaintiff's, with knowledge of the safety and efficacy problems and suppressed this knowledge from the general public. Defendants knew or should have known of the serious health risks it created and/or the failure to comply with federal requirements. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting recipients of Defendants' M2a Magnum Hip System. Defendants' outrageous conduct warrants an award of punitive damages.

RESPONSE: Defendants deny the allegations in Paragraph 118 of Plaintiffs' Complaint.

119. Plaintiff seeks actual and punitive damages from Defendants as alleged herein.

RESPONSE: Defendants deny that Plaintiffs are entitled to the relief requested or any relief at all.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems just and proper.

RESPONSE: Defendants deny that Plaintiffs are entitled to the relief requested or any relief at all.

TENTH CAUSE OF ACTION

(Fraudulent Misrepresentation)

120. Plaintiff incorporates all of the preceding paragraphs of this Complaint as if fully set forth here and further alleges as follows:

RESPONSE: Defendants incorporate by reference their responses to the above paragraphs as if fully set forth herein.

121. Defendants falsely and fraudulently represented to the medical and healthcare community and to Plaintiff, and/or the FDA, and the general public that the subject product had been tested and was found to be safe and/or effective for hip arthroplasty treatment.

RESPONSE: Defendants deny the allegations in Paragraph 121 of Plaintiffs' Complaint.

122. Defendants' representations were false. When said representations were made, Defendants knew those representations were false and Defendants willfully, wantonly and recklessly disregarded whether the representations were true.

RESPONSE: Defendants deny the allegations in Paragraph 122 of Plaintiffs' Complaint.

123. Defendants knowingly and intentionally made false representations of material fact to Plaintiff, including claims that the M2a Magnum Hip System was a safe and durable hip replacement system. Defendants further asserted that the "Biomet metal-on-metal (MoM) M2a Magnum Large Metal articulation system offers optimal joint mechanic restoration and ultra low-wear rates in vivo. Many studies conducted over the last several decades have shown no definitive correlation of negative health issues to ion levels exhibited from metal-on-metal implants."

RESPONSE: Defendants deny the allegations in Paragraph 123 of Plaintiffs' Complaint.

124. Defendants made these representations with the intent of defrauding, and deceiving Plaintiff, the public in general, and the medical and healthcare community in particular, and were made with the intent of inducing the public in general, and the medical and healthcare community in particular, to recommend, prescribe, dispense and/or purchase the M2a Magnum Hip System for hip arthroplasty treatment, all of which evinced a callous, reckless, willful, depraved indifference to the health, safety and welfare of Plaintiff and the public in general.

RESPONSE: Defendants deny the allegations in Paragraph 124 of Plaintiffs' Complaint.

125. At the time the above representations were made by Defendants, and at the time Plaintiff was treated with the M2a Magnum Hip System, Plaintiff was unaware of their falsity and reasonably believed them to be true.

RESPONSE: Defendants deny the allegations in Paragraph 125 of Plaintiffs' Complaint.

126. Relying upon Defendants' representations, Plaintiff was induced to, and did use the M2a Magnum Hip System, thereby sustaining severe and permanent personal injuries including but not limited to significant pain, irritation and discomfort, as well as other severe and permanent health consequences, notwithstanding Defendants' knowledge of an increased risk of these injuries and side effects over other hip arthroplasty devices.

RESPONSE: Defendants deny the allegations in Paragraph 126 of Plaintiffs' Complaint.

127. Defendants knew and were aware or should have been aware that the M2a Magnum Hip System had not been sufficiently tested, was defective in nature, and/or that it lacked adequate and/or sufficient warnings.

RESPONSE: Defendants deny the allegations in Paragraph 127 of Plaintiffs' Complaint.

128. Defendants knew or should have known that the M2a Magnum Hip System could, and would, cause severe and grievous injury to the M2a Magnum Hip System's users, and that it was inherently dangerous in a manner that exceeded any purported, inaccurate, and/or down-played warnings.

RESPONSE: Defendants deny the allegations in Paragraph 128 of Plaintiffs' Complaint.

129. Defendants brought the M2a Magnum Hip System to the market, and acted fraudulently, wantonly and maliciously to Plaintiff's detriment.

RESPONSE: Defendants deny the allegations in Paragraph 129 of Plaintiffs' Complaint.

130. As a direct and proximate result of Defendants' fraudulent misrepresentations and omissions and/or its failure to disclose their violations of federal requirements applicable to the M2a Magnum Hip System, Plaintiff used Defendants' M2a Magnum Hip System and Plaintiff suffered serious physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future. The M2a Magnum Hip System is not subject to federal preemption because it was not approved as an FDA Class III device.

RESPONSE: Defendants deny the allegations in Paragraph 130 of Plaintiffs' Complaint.

131. Defendants' conduct as described above, was extreme and outrageous. Defendants risked the lives of recipients of their products, including Plaintiff's, with knowledge of the safety and efficacy problems and suppressed this knowledge from the general public. Defendants knew or should have known of the serious health risks it created and/or the failure to comply with federal requirements. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting recipients of Defendants' M2a Magnum Hip System. Defendants' outrageous conduct warrants an award of punitive damages.

RESPONSE: Defendants deny the allegations in Paragraph 131 of Plaintiffs' Complaint.

132. Plaintiff seeks actual and punitive damages from Defendants as alleged herein.

RESPONSE: Defendants deny that Plaintiffs are entitled to the relief requested or any relief at all.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems just and proper.

RESPONSE: Defendants deny that Plaintiffs are entitled to the relief requested or any relief at all.

ELEVENTH CAUSE OF ACTION

(Fraudulent Concealment)

133. Plaintiff incorporates all of the preceding paragraphs of this Complaint as if fully set forth here and further alleges as follows:

RESPONSE: Defendants incorporate by reference their responses to the above paragraphs as if fully set forth herein.

134. At all times during the course of dealing between Defendants and Plaintiff, Plaintiff's health care providers, and/or the FDA, Defendants misrepresented the safety of the M2a Magnum Hip System for its intended use.

RESPONSE: Defendants deny the allegations in Paragraph 134 of Plaintiffs' Complaint.

135. Defendants knew or were reckless in not knowing that its representations were false.

RESPONSE: Defendants deny the allegations in Paragraph 135 of Plaintiffs' Complaint.

136. In representations to Plaintiff, Plaintiff's health care providers, and/or the FDA, Defendants fraudulently concealed and intentionally omitted material information, including but not limited to:

a. the M2a Magnum Hip System was not as safe as other similar devices indicated for hip arthroplasty;

b. the M2a Magnum Hip System was defective, and that it caused dangerous side effects, including the risks of developing serious and dangerous side effects such as loosening, component mal-alignment, infections, fracture of the bone, dislocation, metal sensitivity and pain, irritation and discomfort, as well as the need for additional procedures to remove and replace the M2a Magnum Hip System, as well as other severe and permanent health consequences, notwithstanding Defendants' knowledge of an increased risk of these injuries and side effects over other hip arthroplasty devices;

c. the M2a Magnum Hip System was manufactured negligently;

d. the M2a Magnum Hip System was manufactured defectively;

e. the M2a Magnum Hip System was manufactured improperly;

f. the M2a Magnum Hip System was designed negligently;

g. the M2a Magnum Hip System was designed defectively;

h. the M2a Magnum Hip System was designed improperly.

RESPONSE: Defendants deny the allegations in Paragraph 136 of Plaintiffs' Complaint and its subparagraphs (a) – (h).

137. Defendants were under a duty to disclose to Plaintiff, Plaintiff's healthcare providers, and/or the FDA the defective nature of the M2a Magnum Hip System, including the risk of developing elevated metal ion levels, device failure resulting in the need for revision surgery associated with the use of the M2a Magnum Hip System.

RESPONSE: Defendants state that Paragraph 137 of Plaintiffs' Complaint contains legal conclusions to which no response is required. To the extent a response is required, defendants deny the allegations in Paragraph 137 of Plaintiffs' Complaint.

138. Defendants had sole access to material facts concerning the defective nature of the M2a Magnum Hip System and its propensity to cause serious and dangerous side effects, thereby causing damage to M2a Magnum Hip System users, including Plaintiff.

RESPONSE: Defendants deny the allegations in Paragraph 138 of Plaintiffs' Complaint.

139. Defendants' concealment and omissions of material facts concerning, inter alia, the safety of the M2a Magnum Hip System was made purposefully, willfully, wantonly, and/or recklessly to mislead Plaintiff and Plaintiff's healthcare providers into reliance on the M2a Magnum Hip System, and to cause them to purchase, prescribe, dispense and/or use the "M2a Magnum Hip System.

RESPONSE: Defendants deny the allegations in Paragraph 139 of Plaintiffs' Complaint.

140. Defendants knew that Plaintiff, Plaintiff's healthcare providers, and/or the FDA had no way to determine the truth behind Defendants' concealment and omissions as set forth herein.

RESPONSE: Defendants deny the allegations in Paragraph 140 of Plaintiffs' Complaint.

141. Plaintiff, as well as Plaintiff's healthcare providers, reasonably relied on facts revealed which negligently, fraudulently, and/or purposefully did not include facts that Defendants concealed and/or omitted.

RESPONSE: Defendants deny the allegations in Paragraph 141 of Plaintiffs' Complaint.

142. As a direct and proximate result of Defendants' fraudulent misrepresentations and omissions and/or Defendants' failure to disclose its violations of federal requirements applicable to the M2a Magnum Hip System, Plaintiff used the M2a Magnum Hip System and Plaintiff suffered physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future. The M2a Magnum Hip System is not subject to federal preemption because it was not approved as an FDA Class III device.

RESPONSE: Defendants deny the allegations in Paragraph 142 of Plaintiffs' Complaint.

143. Defendants' conduct as described above, was extreme and outrageous. Defendants risked the lives of recipients of their products, including Plaintiff's, with knowledge of the safety and efficacy problems and suppressed this knowledge from the general public.

Defendants knew or should have known of the serious health risks it created and/or the failure to comply with federal requirements. Defendants made conscious decisions not to redesign, re-label, warn or inform the unsuspecting recipients of Defendants' M2a Magnum Hip System. Defendants' outrageous conduct warrants an award of punitive damages.

RESPONSE: Defendants deny the allegations in Paragraph 143 of Plaintiffs' Complaint.

144. Plaintiff seeks actual and punitive damages from Defendants as alleged herein.

RESPONSE: Defendants deny that Plaintiffs are entitled to the relief requested or any relief at all.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems just and proper.

RESPONSE: Defendants deny that Plaintiffs are entitled to the relief requested or any relief at all.

TWELFTH CAUSE OF ACTION

(Punitive Damages)

145. Plaintiff incorporates all of the preceding paragraphs of this Complaint as if fully set forth here and further alleges as follows:

RESPONSE: Defendants incorporate by reference their responses to the above paragraphs as if fully set forth herein.

146. At all times relevant, Defendants knew or should have known that their M2a Magnum Hip System was inherently more dangerous with respect to the risk of significant pain,

irritation, discomfort and need for additional surgeries that the alternative hip arthroplasty systems on the market.

RESPONSE: Defendants deny the allegations in Paragraph 146 of Plaintiffs' Complaint.

147. At all times relevant, Defendants attempted to misrepresent and did misrepresent facts concerning the safety of the M2a Magnum Hip System.

RESPONSE: Defendants deny the allegations in Paragraph 147 of Plaintiffs' Complaint.

148. Defendants' misrepresentations included knowingly withholding material information from the medical community, the general public, and Plaintiff, concerning the safety and efficacy of the M2a Magnum Hip System.

RESPONSE: Defendants deny the allegations in Paragraph 148 of Plaintiffs' Complaint.

149. At all times relevant, Defendants knew and recklessly disregarded the fact that the M2a Magnum Hip System was subject to an increased risk of causing significant pain, irritation, discomfort and need for additional surgeries in persons with M2a Magnum Hip System implants with far greater frequency than safer alternative hip arthroplasty systems.

RESPONSE: Defendants deny the allegations in Paragraph 149 of Plaintiffs' Complaint.

150. Notwithstanding the foregoing, Defendants continued to aggressively market the M2a Magnum Hip System without disclosing the above-mentioned side effects when there were safer alternative methods.

RESPONSE: Defendants deny the allegations in Paragraph 150 of Plaintiffs' Complaint.

151. Defendants knew the M2a Magnum Hip System was defective and unreasonably dangerous. Despite their knowledge, Defendants continued to design, develop, manufacture, market, distribute and sell the M2a Magnum Hip System to maximize sales and profits at the expense of the health and safety of the public, including Plaintiff, in conscious and/or negligent disregard of the foreseeable harm.

RESPONSE: Defendants deny the allegations in Paragraph 151 of Plaintiffs' Complaint.

152. Defendants' intentional and/or reckless, fraudulent and malicious failure to disclose information deprived Plaintiff and her healthcare providers of necessary information to enable them to make an informed decision with regard to using the M2a Magnum Hip System.

RESPONSE: Defendants deny the allegations in Paragraph 152 of Plaintiffs' Complaint.

153. As a direct and proximate result of Defendants' conscious and deliberate disregard for the rights and safety of consumers, Plaintiff suffered severe and permanent physical and emotional injuries. The M2a Magnum Hip System is not subject to federal preemption because it was not approved as an FDA Class III device.

RESPONSE: Defendants deny the allegations in Paragraph 153 of Plaintiffs' Complaint.

154. Defendants' conduct, committed with a knowing, conscious and deliberate disregard for the rights and safety of consumers, including Plaintiff's, entitles Plaintiff to

punitive damages in an amount appropriate to punish Defendants and deter them from similar conduct in the future.

RESPONSE: Defendants deny the allegations in Paragraph 154 of Plaintiffs' Complaint.

155. Plaintiff seeks actual and punitive damages from Defendants as alleged herein.

RESPONSE: Defendants deny that Plaintiffs are entitled to the relief requested or any relief at all.

WHEREFORE, Plaintiff demands judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems just and proper.

RESPONSE: Defendants deny that Plaintiffs are entitled to the relief requested or any relief at all.

THIRTEENTH CAUSE OF ACTION

(Loss Of Consortium)

156. Plaintiffs incorporate all of the preceding paragraphs of this Complaint as if fully set forth here and further alleges as follows:

RESPONSE: Defendants incorporate by reference their responses to the above paragraphs as if fully set forth herein.

157. At all times relevant, Plaintiff Willis William Nicholson was and is the husband of Plaintiff Willis William Nicholson. As such, Plaintiff Willis William Nicholson was and is entitled to his wife's services, support, companionship, affection and consortium.

RESPONSE: Defendants are without knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 157 of Plaintiffs' Complaint and therefore deny the same.

158. As a result of the injuries sustained by his wife as alleged in this Complaint, Plaintiff Willis William Nicholson has lost the services, support, companionship, affection and consortium of his wife, and will continue to lose said services, support, companionship, affection and consortium in the future.

RESPONSE: Defendants deny the allegations in Paragraph 158 of Plaintiffs' Complaint.

159. Plaintiff Willis William Nicholson seeks actual and punitive damages from Defendants as alleged herein.

RESPONSE: Defendants deny the allegations in Paragraph 159 of Plaintiffs' Complaint.

WHEREFORE, Plaintiff Willis William Nicholson demands judgment against Defendants for compensatory and punitive damages, together with interest, costs of suit, attorneys' fees, and all such other relief as the Court deems just and proper.

RESPONSE: Defendants deny that Plaintiffs are entitled to the relief requested or any relief at all.

DEMAND FOR JURY TRIAL

160. Plaintiffs hereby demand a trial by jury on all counts as to all issues.

RESPONSE: The allegations in Paragraph 160 of Plaintiffs' Complaint are not directed at Defendants and therefore no response is required.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs demand judgment against Defendants on each of the above-referenced claims and Causes of Action as follows:

1. Awarding compensatory damages to Plaintiff Lori Nicholson for past and future damages, including but not limited to pain and suffering for severe and permanent personal injuries sustained by Plaintiff Lori Nicholson, health care costs, medical monitoring, together with interest and costs as provided by the law;
2. Awarding compensatory damages to Plaintiff Willis William Nicholson for past and future damages as a result of his loss of consortium;
3. Awarding punitive and/or exemplary damages, in an amount to be determined at trial;
4. Awarding Plaintiff's attorney's fees;
5. Awarding Plaintiff the costs of the proceedings; and
6. Awarding such other and further relief this Court deems just and proper.

RESPONSE: Defendants deny that Plaintiffs are entitled to the relief requested in their Prayer For Relief or any relief at all.

AFFIRMATIVE DEFENSES

Without assuming any burden they would not otherwise bear, Defendants assert the following Affirmative Defenses:

FIRST AFFIRMATIVE DEFENSE

Plaintiffs fail to state a claim against Defendants upon which relief may be granted.

SECOND AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred, in whole or part, by the applicable statute(s) of limitations and/or repose, by the applicable doctrines of laches, waiver, estoppel, and/or illegality.

THIRD AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred, in whole or in part, by the doctrine of res judicata.

FOURTH AFFIRMATIVE DEFENSE

To the extent Plaintiffs are required to plead their claims with sufficient particularity to satisfy the requirements of Fed. R. Civ. P. 9, they have failed to do so and their claims must be dismissed.

FIFTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred, in whole or in part, to the extent they lack standing to pursue the claims alleged against Defendants.

SIXTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred, in whole or in part, by the principles set forth in the Restatement (Second) of Torts § 402A, Comments k and j, and relevant case law upholding and applying those provisions.

SEVENTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred, in whole or in part, by the principles set forth in the Restatement (Third) of Torts: Product Liability, including but not limited to Section 4, Section 6 (including but not limited to §§ 6(c), 6(d), and comment f) and Section 19, and the comments thereto.

EIGHTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred, in whole or in part, by the principles set forth in the Restatement (Second) of Torts Section 388, Comment n and/or similar doctrines and principles contained in the Restatement (Third) of Torts: Products Liability.

NINTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred, in whole or in part, by Defendants' compliance with the state of the art, industry standards, and/or applicable government statutes and regulations.

TENTH AFFIRMATIVE DEFENSE

The injuries and damages claimed by Plaintiffs were not caused by Defendants, but resulted from superseding and/or intervening causes over which Defendants had no control.

ELEVENTH AFFIRMATIVE DEFENSE

If there was any defect in the device – and Defendants deny that there were any defects – there was no causal connection between any alleged defect and the device on the one hand and any damage to Plaintiffs on the other, with the result that Plaintiffs are not entitled to recover against Defendants in this case.

TWELFTH AFFIRMATIVE DEFENSE

Plaintiffs' injuries, losses, or damages, if any, were caused, in whole or in part, by Plaintiffs' own negligence, with the result that Plaintiffs' claims are barred, in whole or in part, by the doctrine of comparative fault.

THIRTEENTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred to the extent that the injuries alleged in the Complaint were caused by the misuse, abnormal use, or use of the device in a manner not intended by Defendants and over which Defendants had no control.

FOURTEENTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred to the extent that the injuries alleged in the Complaint were caused by a substantial change in the device after leaving the possession, custody, and control of Defendants.

FIFTEENTH AFFIRMATIVE DEFENSE

Defendants have no legal relationship or privity with Plaintiffs and owe no duty to Plaintiffs by which liability could be attributed to it.

SIXTEENTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred, in whole or in part, by the learned intermediary and/or sophisticated user doctrine and/or principles to Section 388 of the Restatement (Second) of Torts.

SEVENTEENTH AFFIRMATIVE DEFENSE

Plaintiffs' alleged injuries and damages, if any, were caused directly, solely, and proximately by sensitivities, medical conditions, and idiosyncrasies peculiar to Plaintiffs, not found in the general public, which were unknown, unknowable, or not reasonably foreseeable to Defendants.

EIGHTEENTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred because Plaintiffs were advised of the risks associated with the matters alleged in Plaintiffs' Complaint and knowingly and voluntarily assumed them. Under the doctrine of assumption of the risk, informed consent, release, waiver, or comparative fault, this conduct bars, in whole or in part, the damages that Plaintiffs seek to recover herein.

NINETEENTH AFFIRMATIVE DEFENSE

At all relevant times herein, Plaintiffs' physicians were in the position of sophisticated purchasers, fully knowledgeable and informed with respect to the risks and benefits of the device.

TWENTIETH AFFIRMATIVE DEFENSE

To the extent the claims asserted in the Complaint are based on a theory providing for liability without proof of causation, the claims violate Defendants' rights under the Constitution of the United States and analogous provisions of the applicable states' constitutions.

TWENTY-FIRST AFFIRMATIVE DEFENSE

In the event that it is determined that Plaintiffs are entitled to recover against Defendants, Plaintiffs' recovery should be reduced in proportion to the degree or percentage of negligence, fault, or exposure to products attributable to Plaintiffs or others, including any party immune because bankruptcy renders them immune from further litigation, as well as any party, co-defendant, or non-parties with whom Plaintiffs have settled or may settle in the future.

TWENTY-SECOND AFFIRMATIVE DEFENSE

To the extent applicable, Defendants are entitled to contribution from any person and/or entity whose negligence or other fault contributed to Plaintiffs' alleged injuries and damages.

TWENTY-THIRD AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred, in whole or in part, by Plaintiffs' failure to exercise reasonable care and diligence to mitigate damages, if any.

TWENTY-FOURTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred because the alleged injuries and damages, if any, were caused by medical conditions, diseases, illnesses, or processes (whether pre-existing or contemporaneous) unrelated to Defendants.

TWENTY-FIFTH AFFIRMATIVE DEFENSE

The conduct of Defendants and all activities with respect to the device have been and are under the supervision of the Federal Food and Drug Administration ("FDA"). Accordingly, this action, including any claims for monetary and/or injunctive relief, is barred by the doctrine of primary jurisdiction and exhaustion of administrative remedies.

TWENTY-SIXTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred, in whole or in part, because the manufacturing, labeling, packaging, and any advertising of the product complied with the applicable codes, standards, and regulations established, adopted, promulgated, or approved by any regulatory body with jurisdiction over the product, including but not limited to the United States, any state, and any agency thereof.

TWENTY-SEVENTH AFFIRMATIVE DEFENSE

Plaintiffs cannot show that any reasonable alternative design would have rendered the device to be safer overall under the Restatement (Third) of Product Liability § 2, cmt. F, nor could Defendants have known of any alternative design that may be identified by Plaintiffs.

TWENTY-EIGHTH AFFIRMATIVE DEFENSE

Plaintiffs' product liability causes of action are barred because the benefits of the device outweighed its risks.

TWENTY-NINTH AFFIRMATIVE DEFENSE

No act or omission of Defendants was malicious, willful, wanton, reckless, or grossly negligent, and, therefore, any award of punitive or exemplary damages is barred.

THIRTIETH AFFIRMATIVE DEFENSE

Plaintiffs filed this Complaint in an improper forum, and therefore, venue is improper.

THIRTY-FIRST AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred, in whole or in part, due to the doctrine of spoliation and the failure to properly preserve evidence necessary to the determination of the alleged claims against Defendants.

THIRTY-SECOND AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred by the doctrine of implied preemption to the extent that they are premised on alleged misrepresentations or misstatements to the FDA. *See Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001).

THIRTY-THIRD AFFIRMATIVE DEFENSE

Plaintiffs' claims for punitive or exemplary damages are barred or reduced by applicable law or statute or, in the alternative, are unconstitutional insofar as they violate the due process protections afforded by the United States Constitution, the excessive fines clause of the Eighth Amendment of the United States Constitution, the Commerce Clause of the United States Constitution, and the Full Faith and Credit Clause of the United States Constitution. Any law, statute or other authority purporting to permit the recovery of punitive damages in this case is unconstitutional, facially and as applied, to the extent that, without limitation, it: (1) lacks constitutionally sufficient standards to guide and restrain the jury's discretion in determining whether to award punitive damages and/or the amount, if any; (2) is void for vagueness in that it

failed to provide adequate advance notice as to what conduct will result in punitive damages; (3) unconstitutionally may permit recovery of punitive damages based on out-of-state conduct, conduct that complied with applicable law, or conduct that was not directed, or did not proximately cause harm, to plaintiffs; (4) unconstitutionally may permit recovery of punitive damages in an amount that is not both reasonable and proportionate to the amount of harm, if any, to plaintiffs and to the amount of compensatory damages, if any; (5) unconstitutionally may permit jury consideration of net worth or other financial information relating to Defendants; (6) lacks constitutionally sufficient standards to be applied by the trial court in post-verdict review of any punitive damages award; (7) lacks constitutionally sufficient standards for appellate review of punitive damages awards; and (8) otherwise fails to satisfy Supreme Court precedent, including, without limitation, *Pacific Mutual Life Ins. Co. v. Haslip*, 499 U.S. 1, 111 S. Ct. 1032 (1991); *TXO Production Corp. v. Alliance Resources, Inc*., 509 U.S. 443, 113 S. Ct. 2711 (1993); *BMW of North America, Inc. v. Gore*, 517 U.S. 559, 116 S. Ct. 1589 (1996); and *State Farm Mut. Auto. Ins. Co. v. Campbell*, 538 U.S. 408, 123 S. Ct. 1513 (2003).

THIRTY-FOURTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred, in whole or in part, because Defendants are entitled to the benefit of all defenses and presumptions contained in, or arising from, any rule of law or statute whose substantive law controls the action.

THIRTY-FIFTH AFFIRMATIVE DEFENSE

Plaintiffs' warranty-based claims are barred, in whole or in part, by Plaintiffs' lack of reliance on any such alleged warranties.

THIRTY-SIXTH AFFIRMATIVE DEFENSE

Plaintiffs' warranty-based claims are barred, in whole or in part, by Plaintiffs' failure to satisfy all conditions precedent or subsequent to the enforcement of any such alleged warranties.

THIRTY-SEVENTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred, in whole or in part, because the promotion of the products at issue is protected by the First Amendment of the United States Constitution and similar provisions in applicable State constitutions.

THIRTY-EIGHTH AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred, in whole or in part, by the statutory safe-harbors and/or other provisions in consumer protection and deceptive trade practice laws.

THIRTY-NINTH AFFIRMATIVE DEFENSE

If there was any defect in the device – and Defendants deny that there were any defects – to the extent Plaintiffs, and/or other defendants, and/or third parties for whom or which Defendants were not responsible, failed to observe any obvious defective conditions in any products sold by Biomet, Plaintiffs' recovery against Defendants is barred or must be reduced.

FORTIETH AFFIRMATIVE DEFENSE

Plaintiffs fail to allege facts or state a cause of action against Defendants sufficient to support a claim for attorneys' fees and/or legal costs.

FORTY-FIRST AFFIRMATIVE DEFENSE

Defendants did not violate any statute or law, as alleged by Plaintiffs.

FORTY-SECOND AFFIRMATIVE DEFENSE

Plaintiffs' claims are barred, in whole or in part, by the economic loss doctrine.

RESERVATION OF DEFENSES

Defendants hereby give notice that they intend to rely upon such other affirmative defenses as may become available or apparent during the course of investigation, discovery, or trial, and Defendants reserve the right to amend its Answer to assert such other defenses to which it may be entitled.

REQUEST FOR JURY TRIAL

Defendants seek a trial by jury on all issues so triable.

PRAYER FOR RELIEF

WHEREFORE, Defendants pray for relief from judgment for Plaintiffs as follows:

1. Plaintiffs take nothing by reason of their Complaint;

2. Defendants recover their costs and attorneys' fees incurred herein;

3. For a trial by jury on all issues so triable; and

4. For such further and other relief as the Court deems proper.

DATE: May 22, 2013

By: /s/ Erin Linder Hanig
John D. LaDue
Erin Linder Hanig
LADUE CURRAN & KUEHN LLC
200 First Bank Building
205 West Jefferson Boulevard
South Bend, IN 46601
Tel: (574) 968-0760
jladue@lck-law.com
ehanig@lck-law.com

John D. Winter
Jenya Moshkovich
PATTERSON BELKNAP WEBB & TYLER LLP
1133 Avenue of the Americas
New York, New York 10036
Tel: (212) 336-2000
jwinter@pbwt.com
jmoshkovich@pbwt.com

Attorneys for Defendants

CERTIFICATE OF SERVICE

I certify that on May 22, 2013, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system, which provided electronic service upon all counsel of record.

/s/ Erin Linder Hanig
Erin Linder Hanig (29113-71)